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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,344	11/23/2001	George Jackowski	2132.096	5805

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,344	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/23/03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Claim 1 has been amended and claims 2-38 have been cancelled as requested in the amendment of Paper filed on December 05, 2003. Claims 1 and 39-46 are pending in the instant application.

Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claim 1 is under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 05, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Election/Restrictions

5. Applicant submits that "new claims 39-46 were added in the Response to Restriction Requirement" and not to an action on the merits and refers to MPEP 810 (middle at page 8 of the Response). Applicant's attention is directed to MPEP 821.03 and 37 CRF 1.145, which clearly states:

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will

be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in § § 1.143 and 1.144. Emphasis added by the Examiner.

Claim Rejections - 35 USC § 112

6. Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Applicant's arguments that the instant invention directed to an isolated biopolymer marker peptide of SEQ ID NO: 1, residues 2-18, has a specific substantial and credible utility as a marker for Alzheimer's disease have been found to be persuasive and the rejection under 35 USC § 101 has been withdrawn. However, the Examiner maintains that the instant specification, as filed, fails to provide any guidance on how to use the claimed peptide of SEQ ID NO: 1, residues 2-18, as a marker for Alzheimer's disease, and, therefore does not satisfy the requirements under 35 USC § 112, first paragraph, as indicated in section 6 of Paper No. 12. Applicant's arguments to support the utility of the claimed peptide (pages 12-22 of the Response) are answered in this section as part of the Examiner's response to maintain the instant enablement rejection.

Beginning at page 14, Applicant argues that the instant specification provides "a general disclosure of the protocols and methods used to isolate and identify the claimed biopolymer marker", and further, that electrophoretic, mass spectrometric and chromatographic techniques are well known and disclosed in prior art. The Examiner agrees that the skill in the art is high and

no additional experimentation would be required to practice the well-known protocols used to isolate the instant claimed biopolymer marker. Therefore, The Declaration of Jackowsky under 37 CFR 1.132 filed October 27, 2003 is insufficient to overcome the instant rejection because it does not address any disagreement or an outstanding issue of record. However, the issue at hand remains is not the ability of one to execute a well-known protocol but the ability of one to use the claimed peptide as a diagnostic tool for Alzheimer's disease with a reasonable expectation of success. The Examiner maintains the position, which was fully explained in section 5 of the previous office action, that the instant specification, as filed, fails to provide any evidence or sound scientific reasoning that would support a conclusion that the presence of an isolated peptide consisting of amino acid residues 2-18 of SQE ID NO: 1 in a sample would provide diagnosis of Alzheimer's disease.

Applicant argues that analysis and comparison of the lanes shown in Figure 1 between serum samples of Alzheimer's disease patients and normal control demonstrates that "the down-regulation of the claimed biopolymer marker peptide is indicative of Alzheimer's disease" (pages 16-17 of the Response). Applicant provides explanation of Figure 1, which in summary reflects that bands C1, C2 and C3, which correlate with the claimed biopolymer marker, are strongly present in four age-matched control samples and are absent in four AD samples However, analysis of the data provided in Figure 1 appears to be in conflict with Applicant's statement. Figure 1 is a photograph of a gel containing 10 standard lanes. Lanes 1-4 are AD samples, 5-8 are normal aged control, lane 9 is a pooled normal human serum control and lane 10 is designated for molecular weight standards. Contrary to Applicant's statement that band C2 is "down-regulated" in the first four AD samples, there appears to be no visible difference in

intensity of band C2 in sample 2 (AD sample), samples 6 and 8 (normal age-matched control) and especially, sample 9. Thus, based on the results presented in Figure 1, a skilled practitioner clearly would not be able to distinguish between a normal sample (lane 9) and any of the AD samples, which leads to the conclusion that since the instant specification, as filed, does not provide precise protocol on how to analyze the data obtained by the disclosed protocol, one skilled in the art would clearly have to resort to substantial amount of undue experimentation in order to be able to use the instant claimed peptide 2-18 of SEQ ID NO: 1 as a marker for Alzheimer's disease. Moreover Applicant's current reasoning appears to be in conflict with the Declaration of Lander under 37 CFR 1.132 filed on June 06, 2003, Paper No. 10, which presented information that the instant claimed peptide is not present in normal human serum. In this case, the question would be how to distinguish AD samples and normal "Pooled in-house" samples if both appear to have "less" of biopolymer marker of SEQ ID NO: 1, residues 2-18?

Furthermore, even if to assume that the claimed peptide could be used for diagnosis of Alzheimer's disease, the series of questions regarding the description of the samples used for analysis remains unanswered. The instant specification, as filed, fails to present any description of the samples used in experiments to determine the presence or absence of the claimed marker. There is also no information presented regarding presence or absence of the instant peptide 2-18 of SEQ ID NO: 1 in serum samples of pathological conditions other than Alzheimer's disease, or serum samples of patients suspected of having Alzheimer's disease, in which such marker would be present, followed up by a diagnosis of AD by using other diagnostic methods. A skilled practitioner readily recognizes that in the absence of such critical information Applicant's invention is incomplete, and that it would require a substantial amount of undue experimentation

to discover how to use the claimed biopolymer marker 2-18 of SEQ ID NO: 1 in diagnosis of Alzheimer's disease.

Applicant submits that the references provided in the previous office action, which clearly state that a definitive diagnosis of Alzheimer's disease could be only made during postmortem examination or at brain biopsy, are more than five years old and, therefore, "these references are not considered to accurately assess the state of the art at the time of the Applicant's invention" (bottom at page 19 of the Response). This argument has been fully considered but is not deemed persuasive because the presented references still represent the state of the art in the field of diagnosis of Alzheimer's disease. If Applicant is aware of any art, which was available prior to the filing date of the instant application, which describes any method of definitive diagnosis of Alzheimer's disease by methods other than by direct brain tissue analysis, then Applicant is strongly encouraged to make such art of record. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one

skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed invention without first making a substantial inventive contribution.

Conclusion

7. No claim is allowed.

8. This application contains claims 39-46 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.

JOHN ULM
PRIMARY EXAMINER
GROUP 1600